

MEMORANDUM

DATE: October 31, 2005

TO: Sheila Dearybury Walcoff, Esq.
Associate Commissioner for External Relations
Food and Drug Administration

THROUGH: Jenny Slaughter
Director, Ethics and Integrity Staff
Office of Management Programs, OMS

FROM: Norris Alderson, Ph.D.
Associate Commissioner for Science

SUBJECT: Conflict of Interest Waiver for Barbara McNeil M.D.,
Ph.D.

Barbara McNeil, is a Special Government Employee and a member of the Science Board. This memorandum constitutes a determination, in accordance with 18 U.S.C. 208(b)(3), that the need for Barbara McNeil's participation in particular matters of general applicability, outweighs the potential for a conflict of interest created by any personal or imputed financial interests that she may have in which she is expected to participate.

Particular matters of general applicability may affect certain personal financial interests or the financial interests of the persons and organizations whose interests impute to Gail Cassell under 18 U.S.C. 208. This would include the following:

1. Financial investments in pharmaceutical companies, health care industries, and any other industries that might be affected by participation in particular matters of general applicability such as (____ _ - ____ _).
____ _
____ _).
2. Employment with research institutions, state and local governments, pharmaceutical companies, health care industries or other organizations that may be affected by the committee's recommendations such as her position (____ _ ____ _).
____ _).
3. Grants, contracts, or other funding for research or other services received from the federal government that might be affected by participation in particular matters of general applicability. No such interest currently reported.

4. Grants, contracts, or other funding for research or other services received from non-federal entities, including industries and foundations, that might be affected by participation in particular matters of general applicability. No such interest currently reported.
5. Expert witness, litigation or advocacy services in matters that might be affected by participation in particular matters of general applicability. No such interest currently reported.
6. Any interest of a group or organization in which member is appointed as an officer, director, trustee, employee, or general partner that might be affected by participation in particular matters of general applicability, such as (____).

As a special Government employee, Barbara McNeil potentially could become involved in matters that could affect her financial interests or the financial interests of persons and organizations whose interests impute to her under 18 U.S.C.208. Under 18 U.S.C.208, Barbara McNeil is prohibited from participating personally and substantially in a particular matter affecting those interests. However, you have the authority under 18 U.S.C. 208(b)(3) to grant a waiver permitting her to participate in particular matters of general applicability.

For the following reasons, I believe that it would be appropriate for you to grant a waiver to Barbara McNeil that would permit her to participate in particular matters of general applicability.

First and foremost, this waiver is justified, in part, because of the general nature of particular matters of general applicability. It is well recognized that particular matters of general applicability pose far less risk of a conflict of interest. Particular matters of general applicability include regulations, legislation, guidelines, points-to-consider, and policies governing classes of organizations, individuals, and products. Particular matters of general applicability do not include particular matters involving specific parties, such as specific grants, contracts, recommendations regarding a specific product, or enforcement matters involving known parties. Particular matters of general applicability will not have a unique and distinct impact on any of Barbara McNeil's personal or imputed financial interests, but rather may affect classes of similarly situated products and manufacturers to the same extent.

This waiver is also justified because the Agency has a need for Barbara McNeil's services, in light of her expertise in radiology, and public health policy. Her participation will

contribute to the diversity of views and expertise represented with respect to particular matters of general applicability.

Moreover, Barbara McNeil will be participating in an advisory capacity only. The Food and Drug Administration has sole discretion concerning action to be taken and policy to be expressed on particular matters of general applicability.

Please note that this waiver only allows participation in particular matters of general applicability. It will not allow Barbara McNeil to participate in any matters involving specific parties that may be affected by her financial interests, or the interests of any person or organization described above.

When the matters in which Barbara McNeil may become involved as a special Government employee move from particular matters of general applicability to more specific matters (e.g., recommendations specific to an identified product), which could specifically affect her personal and imputed financial interests, the Food and Drug Administration will examine her interests in relation to the particular matter, and either obtain a specific waiver allowing her to participate, or exclude her from participating in the particular matter.

CONCURRENCE : _____ 11/1/05
Jenny Slaughter Date
Director, Ethics and Integrity Staff
Office of Management Programs

DECISION:

X	General matters waiver granted based on my determination, made in accordance with 18 U.S.C. 208(b)(3), that the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest attributable to the individual.
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Waiver denied.

<u>/S/</u>	<u>11/1/05</u>
Sheila Dearybury Walcoff Esq	Date
Acting Associate Commissioner for	
External Relations	
Food and Drug Administration	